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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,088	10/10/2001	Marie B. Connett-Porceddu	2411-110	4800
6449	7590	04/08/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,088

Applicant(s)

CONNETT-PORCEDDU ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-43 and 45-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-43 and 45-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on December 30, 2003 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/973,088 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1-9, 11-43, and 45-62 are pending.

Claims 10 and 44 have been canceled.

2. Claims 1-9, 11-43, and 45-62 are examined in the present office action.

Specification

3. The use of the trademark MAGENTA, GENETICIN, NESCOFILM, TIMENTIN, NETEX, PECAP, FLUORTEX, GELRITE, AUGMENTIN, and WHATMAN have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9, 11-43, and 45-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levee et al (1999, Molecular Breeding 5(5):429-440).

The claims are drawn to a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* or a method for minimizing damage to transformed cells of pine of the genus *Pinus* subgenus *Pinus* comprising subjecting pine cells to *Agrobacterium* infection, killing, removing or rendering the *Agrobacterium* harmless so as not to damage the growing cells, minimizing damage to cells during and subsequent to *Agrobacterium* treatment by washing cells with a liquid wash medium, rapidly transforming cells, selecting transformed cells, culturing transformed cells to produce transgenic somatic embryos and growing somatic embryos into transgenic plants. The claims are also drawn to a method comprising a support membrane onto which the *Pinus* cells are placed and the membrane is used to move the cells to and from the transformation stage of the process; to the step in which the *Agrobacterium* is killed or rendered harmless or removed from said cells; to the step of growing the embryogenic cells into somatic embryos, wherein the removal of *Agrobacterium* involves washing said cells with a liquid wash medium anywhere from 2 to 10 times, wherein each wash is carried out for a time between a half hour to overnight, and wherein the support membrane is prepared from polyester, polypropylene, or a liquid permeable fluoropolymer fabric. Applicants' claims are also drawn to culturing co-cultivated cells on a support membrane placed over a gel medium, wherein a selection agent is contained within said gel medium or said support membrane is placed over a layer which is over a gel medium, wherein said layer is a layer of liquid medium or wherein said

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layer is a filter paper with a liquid medium absorbed therein, wherein said layer also comprises an chemical to eradicate the *Agrobacterium*. Applicants' claims are also drawn to a method for pine cell tissue culture which comprises culturing pine cells of the genus *Pinus* subgenus *Pinus* on a support membrane placed over a gel medium, wherein the support membrane is placed over a layer containing one or more tissue culture medium components, said layer is positioned on said gel medium, wherein said layer is a liquid layer, or wherein said layer is a filter paper with a liquid medium absorbed therein, wherein said membrane is prepared from polyester, polypropylene, or a liquid permeable fluoropolymer fabric.

Levee et al teach a method of stable transformation of *Pinus strobes* after co-cultivation of embryogenic tissues with *Agrobacterium* in which a support membrane is used. The method of Levee et al involves subculturing embryogenic tissues in liquid medium where they are suspended in said medium. *Agrobacterium* cells are grown to a particular titer and then equal volumes of the two solutions are mixed. For the co-cultivation step, the mixture is spread on filter paper and the liquid medium is removed by a low-pressure pulse using a Buchner funnel. The filter paper with *Agrobacterium* and *Pinus* cells is placed in a Petri dish containing a semi solid medium. Embryogenic tissues are co-cultivated with *Agrobacterium* for two days. After co-cultivation, the embryogenic tissue is washed in 100 ml of water to remove *Agrobacterium* and then with a tetracycline solution to kill or eradicate the *Agrobacterium*. The cells are collected onto a support membrane which is placed onto a medium containing a chemical toxic to the bacteria but which allows the embryogenic cells to grow. After a week, the support membrane with embryogenic cells is transferred onto a selective medium (containing Kanamycin) to select for transformed *Pinus* cells. Kanamycin-resistant cell lines are then

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isolated and allowed to grow into somatic embryos and finally into plants (page 431, left column, under "transformation procedure").

Levee et al does not teach a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus*, or varying the time the cells are washed to between half an hour to overnight, using a support membrane made from polyester, polypropylene or liquid permeable fluoropolymer fabric, a filter paper absorbed with a selection agent, a filter paper absorbed with an eradicator, placing the support membrane over a thin film of liquid medium or over filter paper with liquid medium absorbed therein, and placing the selection agent in a thin film of liquid medium

Given the recognition of those of ordinary skill in the art of the value of producing a transformed pine plant comprising co-cultivating *Agrobacterium* with embryogenic pine tissue or cells in a liquid medium and then harvesting cells onto a support membrane which is used to transfer the cell to different media for the purpose of growing pine cells, eradicating *Agrobacterium* and selecting transformed embryogenic tissue, as taught by Levee et al, it would have been obvious to incorporate this method for use on pine cells/plants of the genus *Pinus* subgenus *Pinus*, given the lack of evidence to the contrary that one type of pine plant is different from another, and to optimize this method by optimization of process parameters that would not confer patentable distinction on the claimed invention. The optimization of process parameters process involves varying the wash time of the cells from between half an hour to overnight; using a support membrane made from different polymers which include, polyester, polypropylene, or a liquid permeable fluoropolymer fabric; using a filter paper absorbed with a

selection agent or an eradicator; and placing the support membrane over a film of liquid comprising a liquid medium, selective agent or eradicator.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant remarks/Office response for 103 Rejection

Applicant's arguments filed 12/30/2003 have been fully considered but they are not persuasive.

Applicants contend that claims 1 and 25 now recite that to minimize damage to cells subsequent to *Agrobacterium* infection, the cells are washed with a liquid wash medium. Applicants state that during the interview with Dr. Connett-Porceddu, it was disclosed that distilled water could not be used to successfully wash cells, but that any liquid wash medium could be used. Applicants contend there is no suggestion in Levee et al to use a liquid wash medium and no suggestion that use of a liquid wash medium would result in an enhanced transformation and regeneration of transformed embryogenic tissue of hard pines (page 14, 1st full paragraph). Applicants contend that Levee et al disclose *Agrobacterium* transformation of white pine which is a soft pine and not a hard pine (page 14, 2nd paragraph). Applicants contend that the instant application is directed to transformation and regeneration of a hard pine species. Applicants contend that in order to further establish the known differences between hard and soft pines and to provide further evidence of the non-obviousness of the present invention, Applicants are in the process of preparing a Rule 132 Declaration, which will be submitted (page 16, top paragraph).

The Office contends, the recitation "a wash medium" encompasses water, given the lack of description of this term in the specification. Given that "a wash medium" encompasses water, the teachings of Levee et al, make obvious the claimed invention. A submission of a 1.132 Declaration specifying the differences between transforming and regenerating hard and soft pines and why the Office should not consider the Levee et al reference as making obvious the claimed invention, will be considered.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 52-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 31, and 33-37 of copending Application No. 09/973,089. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 31, and 33-36 of application number 09/973,089 are drawn to a method of regenerating transformed pine plants from transformed cells of the genus *Pinus* subgenus *Pinus* (including Southern Yellow pine)

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comprising selecting transformed pine cells on a medium comprising a selection agent and wherein the selection agent is contained in a layer and said cells are cultured on a support membrane placed over said layer, or wherein said layer is a liquid layer, or wherein said layer is a filter paper with a liquid medium absorbed therein, wherein said support membrane is made from polyester, polypropylene or liquid permeable fluoropolymer fabric.

Claims 52-57 of the instant application are obvious over claims 1, 3, 31, and 33-37 of application '089 because the instant claims are drawn to a method for selecting transformed pine cells of the genus *Pinus* subgenus *Pinus* comprising culturing said transformed pine cells on a support membrane placed over a gel medium or placed over a layer which is over said medium wherein said medium comprises tissue culture constituents and wherein said layer is liquid and wherein said membrane is from polyester, polypropylene or liquid permeable fluoropolymer fabric, and wherein a selection agent is contained within said gel medium or said layer. It would have been obvious to one of skill in the art to modify the method from the '089 application by incorporating other members of the genus *Pinus* subgenus *Pinus* and other known differentiation and regeneration agents, given the recognition by those of ordinary skill in the art of the value of obtaining whole transformed pine plants for lumber.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

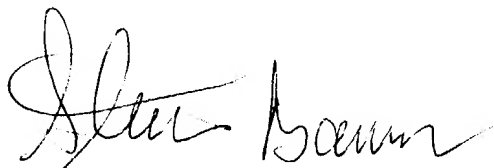
6. No claims are allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with the first name "Stuart" being more prominent and the last name "Baum" following in a similar style.

Stuart F. Baum Ph.D.
Patent Examiner
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April 5, 2004